IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GAYNELL GRIER, et al., individually and on behalf of others similarly situated, Plaintiffs,	)	
and	)	Case No. 3:79-3107
	)	Judge Nixon
SANFORD BLOCH, et al., and all others similarly situated, Plaintiffs-Intervenors,	)	Class Action
v.	)	
M.D. GOETZ, JR., Commissioner, Tennessee Department of Finance and Administration, et al., Defendants,	)	
and	)	
TENNESSEE ASSOCIATION OF HEALTH MAINTENANCE ORGANIZATIONS, et al., Defendants-Intervenors.	)	

ORDER

Pending before the Court is Plaintiffs' Motion For Clarification (Doc. No. 1287), to which Defendants have responded in opposition (Doc. No. 1297), and Plaintiffs-Intervenors have replied principally in opposition (Doc. No. 1314). Plaintiffs also filed a Supplement to Memorandum in Support of Motion for Clarification (Doc. No. 1325), as well as a Notice attaching the Public Necessity Rules which Amend TennCare Rules 1200-13-13-.01. -.03, -.05, -.08, -.11, and -.13. Plaintiffs request four clarifications of this Court's Revised Order (Doc. No. 1256) and Memorandum (Doc. No. 1282). The Court will address each in turn.

1. Does paragraph (vii) of the Revised Order (Doc. No. 1256) allow the State to NOT provide notice of right to appeal and opportunity for fair hearing when a TennCare pharmacy denies or refuses an enrollee a three-day emergency supply of prescribed medication?

Paragraph (vii) of the Revised Order permits the State to refuse to dispense a prescribed drug that lacks the requisite prior authorization, except that a pharmacist may dispense a 72-hour emergency supply of the drug. (Doc. No. 1256 at 8.) Plaintiffs propose that in the event the pharmacist denies or refuses to dispense a 72-hour emergency supply of a prescribed drug that lacks the requisite authorization, the enrollee should be provided with a notice of the right to an appeal and an opportunity for a fair hearing. Plaintiffs cite to 42 C.F.R. §§ 431.206, 431.210, 431.220, 431.232 and 431.241 to support their position. These federal regulations are inapplicable to a pharmacist's refusal to dispense a 72-hour emergency supply of a prescription drug lacking the requisite authorization.

First, § 431.232 and § 431.241 relate to adverse decisions resulting from local evidentiary hearings and matters to be heard at such hearings. An "evidentiary hearing" is defined as "a hearing conducted so that evidence may be presented." 42 C.F.R. § 431.201. A decision by a pharmacist not to dispense a 72-hour emergency supply of a drug does not constitute a hearing at which evidence is presented. Second, § 431.206(c)(2) requires notice and a hearing "[a]t the time of any action affecting" an enrollee's claim. Similarly, § 431.220(a)(1) requires an opportunity for a hearing when an enrollee's "claim is denied or is not acted upon with reasonable promptness." In the prior authorization context, the "claim" for services is the request that prior authorization for a prescription drug be granted. The dispensation of a 72-hour emergency supply is not a separate "claim" for services, but is part of the prior authorization process. (See Doc. No. 1282 at 48-49 (finding that emergency supply is dispensed in the middle

of the prior authorization process).) Therefore, once the prior authorization process has been triggered, the denial of prior authorization (and not the refusal to dispense a 72-hour emergency supply) represents the "action affecting," "denial" of, or failure to act with "reasonable promptness" on, the claim from which an enrollee is entitled to appeal. See §§ 431.206(c)(2), 431.220(a)(1). Section 431.220(a)(2) permitting an enrollee to appeal whenever "he or she believes the agency has taken action erroneously" is also inapplicable because an "action" can only be taking when a "claim" is pending. As noted, the "claim" is the request for prior authorization and the resulting "action" is the denial of prior authorization. Thus, federal regulations do not require notice of appeal and an opportunity for a hearing when a pharmacist refuses to dispense a 72-hour emergency supply.

In the event an enrollee appeals the denial of prior authorization, the enrollee may raise any alleged deficiencies in the prior authorization process, including the pharmacist's refusal to dispense an emergency supply, during that appeal. Notice that an enrollee may raise all complaints about the prior authorization process in an appeal, including a pharmacist's refusal to dispense an emergency supply, must be provided in the same notice informing the enrollee of his or her right to appeal the denial of prior authorization. § 431.210; (see Doc. No. 1282 at 63-65.)

Plaintiffs further argue that Paragraph C(14)(a)(iv) of the 2003 Consent Decree[1] requires the pharmacist to provide an enrollee with written notice of the right to receive an interim supply and "what to do if he does not receive such an interim supply." Paragraph C(14)(a)(iv) applies to the "interim" supply of prescribed drugs lacking prior authorization rather than the 72-hour

[1] Terms used but not defined herein shall have the same meaning attributed to them in the Court's Memorandum (Doc. No. 1282).

emergency supply that is now required. As an "interim" supply is no longer required, Paragraph C(14)(a)(iv) of the 2003 Consent Decree must be modified or deleted to conform with the new 72-hour emergency supply requirement.

While it would behoove the State to continue to provide a "what to do" notice, neither Paragraph C(14)(a)(iv) nor federal regulations require a notice of "appeal." Rather, the "what to do" notice may inform the enrollee that to ensure a 72-hour emergency supply, the enrollee should contact his or her physician to obtain an emergency prescription; telephonically contact the State's PBM and ask for a second determination whether an emergency exists; or wait for further notification explaining whether prior authorization has been granted or denied for the entire prescription. The notice may also include transportation information, as currently required by Paragraph C(14)(a)(iv).

Finally, Plaintiffs argue that notices and hearings are the only practical means for monitoring compliance with the requirement to provide enrollees a 72-hour emergency supply of a drug for which prior authorization is required, but has not been obtained. Appeals are not the only method of monitoring compliance. The State may implement less costly and time-consuming monitoring requirements, such as requiring the pharmacist to submit an explanation each time an emergency supply is not provided.

For these reasons, the Court **HOLDS** that the State is not required to provide a notice of right to appeal and opportunity for fair hearing when a TennCare pharmacy denies or refuses an enrollee a 72-hour emergency supply of prescribed drug lacking the requisite prior authorization.

2. Does paragraph (xv) of the Revised Order (Doc. No 1256) allow the State to appeal a medical appeal decision WITHOUT written notice to the enrollee of the reasons for the appeal?

Paragraph (xv) of the Revised Order permits the State to appeal a non-TennCare official's decision at any stage during a medical appeal. (Doc. No. 1256.) Plaintiffs argue that 42 C.F.R. §§ 431.206(c)(2), 431.210, 431.244(a) and (c) require the State to provide enrollees a copy of the State's written request for review of a non-TennCare official's hearing decision by the Commissioner's designee. These federal regulations require the State to provide notice to an enrollee "[a]t the time of any action affecting" the enrollee's claim for services. 42 C.F.R. § 431.206(c)(2). The "action" affecting the enrollee's claim for services, however, is not the State's decision to appeal a non-TennCare officer's decision, but the initial termination, suspension, reduction, delay, denial, impairment or interruption of the service that led to the hearing in the first instance. Importantly, pursuant to 42 C.F.R. § 431.10(e)(3) a decision by a non-TennCare official is not final until it is approved by the single state agency. Indeed, when read together, §§ 431.206(c)(2) and 431.10(e)(3) require the State to inform the enrollee at the time an appeal is initiated that any decision made by a non-TennCare official is not final until approved by the single state agency. This Court, however, could find no federal mandate requiring the State to provide enrollees a copy of the State's written request for review of a non-TennCare official's decision by the Commissioner's designee.

Plaintiffs argue that there is a state mandate to provide written notice of the Bureau of TennCare's review of a non-TennCare official's decision. See Tenn. Code Ann. § 4-5-314, 4-5-315. Section 4-5-315 permits a state agency to review an administrative law judge's initial order. To do so, the state agency must provide written notice of its intent to review the initial

order within fifteen days after the order's entry. Further, the state agency is required to permit the party to submit additional briefs and present oral argument, although no specific time frame is provided for such briefs and argument to be presented. § 4-5-315(e). The agency is then required to render a final order within sixty days. § 4-5-315(h). Plaintiffs state that they do not object "to the reduction of time from 15 to 5 days within which the State must request and complete the review of the initial order." (Doc. No. 1325 at 5.) However, § 4-5-315 does not require completion of the review of the initial order within fifteen days. Rather, it requires fifteen days notice of an intent to review the initial order. Indeed, setting aside the fifteen day notice period and the indeterminate amount of time permitted to file briefs and present oral argument, § 4-5-315(h) provides the state agency with sixty days to complete review of the initial order.

The timing requirements of § 4-5-315 appear to be incompatible with federal regulations requiring final action within ninety days in a standard medical appeal, see 42 C.F.R. § 431.244(f), and the 2003 Consent Decree requiring final action within thirty-one days in an expedited medical appeal, (see Doc. No. 908 ¶16(f)). In addition to the inconsistency in timing, federal regulations only require one hearing, see 42 C.F.R. § 431.244, whereas § 4-5-315 permits "oral argument" in an appeal of the initial order. Nevertheless, Plaintiffs request this Court to impose the notice requirement of § 4-5-315, but at the same time ignore its timing and hearing requirements. The Court is not at liberty to cherry pick provisions of a statute it wishes to apply, while ignoring others. Importantly, where one state statute implementing Medicaid requirements conflicts with a separate state statute regarding general administrative requirements, the former statute controls. See Prior v. Ohio Dep't of Human Services, 123 Ohio App.3d 381, 387 (Ohio

Ct. App. 1997); see also Westside Mothers v. Haveman, 289 F.3d 852, 859-60 (6th Cir. 2002) (stating that Medicaid requirements invalidate conflicting state law).

Thus, the Court **HOLDS** that the State may appeal a non-TennCare official's medical appeal decision without written notice to the enrollee of the reasons for the appeal. The State must, however, provide the enrollee its reasons for overruling a non-TennCare official's decision once the decision has been made, as the State has already agreed to do. (Doc. No. 1297 at 7.)[2]

3. Do paragraphs (xvi) and (xvii) of the Revised Order (Doc. No 1256) eliminate the sanctions under Paragraph C(16)(a) and C(16)(b) of the 2003 Consent Decree (Doc. No. 908 at 27-28)?[3]

In balancing fundamental due process requirements with the State's need to create a fiscally responsible administration of TennCare, the Court permitted the State to modify Paragraph C(16) of the 2003 Consent Decree "to ensure sufficient time to obtain the enrollees' medical records," and permitted a defect in a notice or a missed deadline to be remedied by re-issuing a notice or delaying the deadline only in the event that such defect or missed deadline

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[2] The problem with this issue appears to be the difficulty in balancing due process requirements with the practical and federal regulatory time constraints the State faces in resolving appeals. The Court urges the parties to craft a solution that will adhere to federal regulations delineating the outer time limits required to complete an appeal (ninety days or less depending on the type of appeal), while at the same time follow the due process spirit of § 4-5-315. As an aside, the Court notes that it did not "hold" that prompt corrective action must take place within five days, it simply found no justification to modify Paragraph C(16)(c) of the 2003 Consent Decree. (Doc. No. 1282 at 92.) Thus, in considering a different approach the parties may wish to extend the time to render corrective action, as long as such extension falls within the confines of what is generally considered to be "prompt."

[3] The Court has combined Plaintiffs' requests (3) and (4), as both relate to the elimination of sanctions.

occurred at an early stage of an appeal. (Doc. No. 1256 ¶¶ (xvi)(1), (xvii), at 13-14.) In its Memorandum, the Court explained:

> Once the State or its contractors has issued a revised notice or statement of reasons or legal authorities, it shall be bound by that notice and may not issue a third revised notice. To do so would be to permit the State and its contractors to revert to the practices this Court previously found impermissible. In addition, the State may not remedy a defective notice at a later stage in the appeals process because this risks delaying the appeals process in violation of 42 C.F.R. § 431.244(f) and would deprive TennCare enrollees of fundamental due process rights. See Ortiz v. Eichler, 616 F. Supp. 1046, 1063 (D. Del. 1985); see also Goldberg v. Kelly, 397 U.S. 254, 267-268 (1970). This ruling also extends to remedying missed appeals deadlines, and Paragraphs C(1)(f)-(g) may be revised to reflect this ruling.

(Doc. No. 1282 at 100.) Thus, as a general matter, defects in notices or missed deadlines in the early stages of an appeal may be remedied without imposing the sanction of automatically granting the requested service. The Court, however, did not modify the 2003 Consent Decree's sanction regime for defects in notices or missed deadlines occurring in the later stages of an appeal. Therefore, in the event a defect in a notice or missed deadline occurs in the later stages of an appeal, the sanction of automatically granting the requested service remains. Indeed, the Court finds that the sanction must remain to avoid reverting to practices permitted prior to the 2000 Consent Decree. (Id. (quoting Doc. No. 868 at 16).)

a. Sanction Pursuant To Paragraph C(16)(a) Of The 2003 Consent Decree

Turning to specifics. Plaintiffs' request (3) asks whether paragraphs (xvi) and (xvii) of the Revised Order eliminate the sanction under Paragraph C(16)(a) of the 2003 Consent Decree. Paragraph C(16)(a) states: "the failure of an MCC to act upon a request for prior approval within 21 days shall result in automatic authorization of the requested service." (Doc. No. 908 at

27) (emphasis added).[4] First, paragraphs (xvi) and (xvii) of the Revised Order relate to the appeals process, and not to MCC prior approval. (Doc. No. 1256 at 13-14.) Second, the State made thirty-four requests for modification of the 2003 Consent Decree, and ten requests for clarification of this Court's subsequent Orders, and not a single request relates to MCC prior approval or Paragraph C(16)(a). (See Doc. Nos. 1086, 1087, 1250.) Accordingly, there was no request for modification of Paragraph C(16)(a), and the Court did not modify it.

Furthermore, the Court sees no reason to sua sponte modify this provision. The twenty-one-day time period provides MCCs with ample time to obtain and review medical records to make a decision regarding a prior approval request. Even if that time has now been reduced by consent between the parties to fourteen days, see Paragraph (7) of rule 1200-13-13-.11, that should be sufficient time to make a prior approval decision. Indeed, MCCs are required to make reconsideration decisions within fourteen days in the case of standard appeals. (Doc. No. 1282 at 93.) Thus, the Court **HOLDS** that Paragraph C(16)(a) has not been modified and the sanction remains.

b. Sanction Pursuant To Paragraph C(16)(b) Of The 2003 Consent Decree

Plaintiffs' request (4) asks whether paragraphs (xvi) and (xvii) of the Revised Order eliminate the sanction under Paragraph C(16)(b) of the 2003 Consent Decree. Paragraph C(16)(b) states, in relevant part: "If an MCC fails to complete reconsideration of an appeal

[4] The Court notes an inconsistency between the 2003 Consent Decree permitting MCCs to rule on prior approval requests within twenty-one days, and Paragraph (7) of rule 1200-13-13-.11, which now requires such a decision within fourteen days.

within the required time, the defendants shall immediately resolve the appeal in favor of the beneficiary . . . ." (Doc. No. 908 at 28.) Again, the Defendants did not request an elimination of these sanctions in their requests for modification. (See Doc. Nos. 1086, 1087.) Rather, in their request (p), Defendants requested the authority to "revise the time limitations for filing and resolving medical appeals to conform with federal requirements, and the State may limit expedited appeals to circumstances as required by federal regulations." (Doc. No. 1086 at 5.) Additionally, in their request (q), Defendants requested the authority to "remedy any defect in a required notice or statement of reasons or legal authorities by providing a corrected notice or statement . . . ." (Id.) Neither of these requests addressed the sanction resulting from a missed deadline. In a request for clarification, however, Defendants asked whether the Court's ruling on request (q) applied "to situations in which an appeal deadline has been missed such that coverage will not automatically be determined just because a deadline has been missed?" (Doc. No. 1250.) In its Revised Order, the Court stated that "Defendant's request (q) . . . as well as its clarification to remedy a missed appeal deadline is GRANTED in part." (Doc. No. 1256 ¶ (xvii), at 14.) The Court went on to explain that a missed deadline could be remedied only in the early stages of an appeal. (Id.) Implicit in the Court's holding was that the "remedy" to a missed deadline would be the extension of the deadline without imposition of the sanction.

Thus, the sole issue that needs to be clarified is whether MCC reconsideration occurs in the "early stages of an appeal." MCC reconsideration is requested at the very beginning of the appeals process. (Def. Ex. 251.) Accordingly, the Court **HOLDS** that MCC reconsideration occurs in the "early stages of an appeal," and missing this deadline should not result in the sanction of automatically granting the requested service. Nevertheless, the Court is wary of

returning to a pre-2000 Consent Decree manner of operating where the State and MCCs routinely failed to meet deadlines. Thus, the Court **ORDERS** the Plaintiffs and Defendants to discuss alternative incentives or penalties that could be imposed to reduce the number of deadlines missed, and present any alternative(s) to the Court along with the modifications to the 2003 Consent Decree.

It is so ORDERED.

Entered this the 31st day of January, 2006.

JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT